Question from Senator John Boozman

Question 1: I want to thank the VA for your foresight and leadership on S. 769, The Medicare Access to Radiology Care Act of 2017, to require Medicare to recognize RAs. The VA has indicated that they are in the process of authorizing Radiology Assistants at the VA to align Medicare requirements with state requirements. Will you provide a status update for this effort and your sense as to when this process will be completed?

<u>VA Response:</u> The Department of Veterans Affairs (VA) Office of Human Resources and Administration (HRA) is in the process of establishing a new qualification standard for the Registered Radiologist Assistant. Currently, the qualification standard is in the final stages of concurrence for approval and publication. The qualification standard provides that a Registered Radiologist Assistant practices under the direction and supervision of a physician. HRA is working towards having this qualification standard completed by November 2018.

Question from Senator Sherrod Brown

Question 2: I am very happy the Committee will review two different pieces of legislation to address the needs of active duty servicemembers as they transition to civilian life. We need to do everything we can to ensure that they have the information and tools that they need to succeed. Additional days of training to pursue education, technical training, or entrepreneurship will help to set servicemembers up for good paying jobs when they reenter civilian life and I was pleased that this year's NDAA included a version of this provision in the final conference report. Under Secretary Lawrence, in your testimony, you say we need to do more to communicate with veterans after they transition because rapid identification of risk from transition does not present until much later. Are you referring to the VFW's suggestion that TAP programs should be offered to veterans once they have reintegrated in their communities? Are you referring to risk for medical/ mental issues, unemployment? Walk me through what you mean by that.

<u>VA Response</u>: VA agrees with our Veterans Service Organization partners that consideration must be given to assist transitioning Servicemembers to identify and connect with resources within their new civilian communities – wherever they choose to live. However, VA is not referring to offering Transition Assistance Programs (TAP) to Veterans once they have reintegrated into their communities. To that end, VA and its TAP interagency partners are currently developing a Military Life Cycle module that will introduce transitioning Servicemembers to resources located in their civilian communities and inform them on how to connect with those resources. VA will complete development of this module by December 2018 and will be ready to pilot in

coordination with the Department of Defense (DoD) and the military services beginning in January 2019.

Moreover, with regard to Servicemembers who are at-risk for challenges during their transition, VA and its TAP interagency partners recognize the need to be available during the entire transition to civilian life. As such, we are working to implement Executive Order 13822, "Supporting Our Veterans During Their Transition from Uniformed Service to Civilian Life," to ensure these at-risk transitioning Servicemembers are identified and receive a warm handover to the support they need. However, VA notes that the signs and symptoms associated with these areas of risk do not always appear or begin until after transition from military service. The delayed onset of symptoms presents challenges for VA and other agencies, as there are times when the Government does not have regular contact with the transitioning Servicemember/Veteran.

In keeping with our enduring commitment to those who have worn the uniform, VA and its Federal partners have developed a Joint Action Plan which, when fully implemented by July 2019, will improve our ability to provide a seamless handoff to VA and ensure early and consistent contact with Veterans to keep them informed of access to peer support, availability of mental health care after separation, and eligibility for health care and VA benefits.

Questions from Senator Joe Manchin

Question 3: In your testimony on S. 1592 VA Financial Accountability Act of 2017, you stated an independent review of VA financial processes would be redundant and that the VA's Enrollee Health Care Projection Model (EHCPM) has been extensively reviewed. The two reports you cited, a GAO report and a report by The RAND Corporation are from 2008 and 2011 however, i.e. well before the VA Choice Program was enacted. One of the conclusions of the 2008 RAND report was that the EHCPM model could yield misleading results, especially in a changing policy and budgetary environment.

<u>Question 3a:</u> Has the EHCPM been updated to model the changing demand for healthcare obtained outside of the VA system through Choice and other community care initiatives?

<u>VA Response:</u> Yes, the 2016 Enrollee Health Care Projection Model (EHCPM) that informed the 2019 President's Budget was enhanced to differentiate health care provided in VA facilities and care purchased in the community. Key enhancements included developing unit costs that reflect what VA is expected to pay for purchased care and differentiating reliance and other assumptions in the EHCPM by location of care.

The EHCPM has been enhanced to model changes in Veteran demand for VA health care recognizing that greater access to care in the community closer to the enrollee's home is expected to increase enrollee reliance on VA health care and the proportion of that care expected to be met outside of the VA system through community care. Since enrollees currently rely on VA for less than 40 percent of their health care, small changes in reliance can have a significant impact on expenditure requirements.

The total enrollee demand for VA health care projected by the EHCPM can be reported separately for care expected to be provided in VA facilities and expected to be purchased in the community. However, the proportion of total care that will be provided in VA facilities and purchased in the community can vary significantly depending upon eligibility criteria, operational guidelines, and resource availability.

Question 3b: Has EHCPM been reviewed, by an independent body, since the VA Choice program was enacted?

<u>VA Response:</u> The EHCPM has been reviewed extensively by independent stakeholders, including the Office of Management and Budget, Congressional staff, the Congressional Budget Office, and the Government Accountability Office (GAO). GAO, which reviewed the EHCPM in 2011, is currently reviewing the EHCPM as part their review of the VA Community Care Budget (GAO Report 102732). VA is providing extensive information on the enhancements to the EHCPM in order to differentiate health care provided in VA facilities and purchased in the community and will address any recommendations included in GAO's final report.

Question 3c: Given the sweeping reforms that are part of the VA MISSION Act doesn't make sense to have a new, independent review of the VA's cost projection models?

VA Response: Please see response to Question 3b.

Question 4: In your testimony, you state that the Blue Water Navy bill would add significantly to the number of benefit claims pending over 125 days and additional employees would have to be hired to handle the case load. How many people would you need to hire if the bill passed into law?

<u>VA Response:</u> The Veterans Benefits Administration (VBA) would require an additional 803 full-time employees (FTE) for 2019 to successfully and timely address any new reviews and claims that would be a result of the bill passing into law.

Question 5: In the introduction of the 2011 Institute of Medicine (IOM) report on Blue Water Navy, they say the following in the introduction: "The committee was surprised and disheartened to find a dearth of information on environmental concentrations of TCDD during the Vietnam War, in spite of large volumes of

Agent Orange sprayed throughout South Vietnam. Such information is vital to determining possible exposures not only of Navy veterans but also veterans who served on the ground and on the land waterways of Vietnam." Can you elaborate on ways the Department of Defense and Department of Veterans Affairs have improved service record keeping and transfers of information so that they accurately reflect possible toxic exposures while in service?

<u>VA Response:</u> VA defers to DoD for a full description of initiatives and efforts to improve recordkeeping of military exposure events. However, VA and DoD work closely to identify situations where Servicemembers may be at risk. The Deployment Health Working Group, comprised of both DoD and VA officials, meets monthly to discuss ongoing and emerging environmental issues and oversees development of initiatives to improve interagency sharing of vital information.

The Individual Longitudinal Exposure Record (ILER) is an example of an ongoing joint enterprise initiative between DoD and VA. The purpose of this initiative is to establish a complete record of every Servicemember's exposure over the course of his or her career. ILER will provide a real-time, long-term exposure record matched to health status and matched to a Servicemember to a place, time, location, and event.

Question from Senator Mazie Hirono

Question 6: Dr. Lawrence, you state in your testimony that increasing the amount of DIC benefits payment will help survivors continue to live a sustainable life, which I wholeheartedly agree with. Are there any other programs under your purview which need a fresh look at changing the formula for calculating payments similar to how S. 1990 does for DIC payments?

<u>VA Response:</u> Yes, the VA legislative proposals published in the Fiscal Year 2019 President's Budget address identified areas for improvement in how VA calculates and provides benefits, including proposals pertaining to: (1) the reissuance of VA benefit payments to all victims of fiduciary misuse; and (2) the removal of annual income from net worth calculations for pension benefits.

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Additional Questions for the Record from Senator Sherrod Brown

Blue Water Navy

Mr. Manar's testimony is very convincing, and so was the Australian study. "If there was dioxin in the water, we would have been exposed to it while swimming. Week after week, patrolling up and down the coast, we took in sea water and processed it through our fresh water evaporator system. We know from the Australian Navy study, validated by the National Academy of Medicine (formerly the Institute of Medicine), that fresh water evaporator systems concentrated toxic material, including dioxin, which was then transmitted to sailors through drinking water.¹

As a matter of observation, absent the cleaning and sanitation of the entire fresh water evaporator system, it is conceivable that every person who ever served on board my ship could have been exposed to dioxin after its first visit to Vietnam. Further, by the time we completed our last deployment to Vietnam in 1972, the evaporator system would have accumulated concentrated dioxin from dozens of visits to Vietnam, not simply the final three that I experienced while on board."

Question 1: Dr. Erickson, to date, why hasn't VA concluded that the science behind the Australian study, which NAM corroborated, is sufficient? What additional science is VA waiting for?

VA Response: We thank the Senator for this question and for his careful consideration of the evidence underlying this bill. We recognize that this is a complex exposure issue that is important to our Veterans, and we have been working diligently over the years to gain as much understanding as possible and to recommend policies that are facts based. The Senator has noted that he finds both the Australian study and the Veteran's testimony to be strong evidence in support of concluding that Blue Water Navy Veterans were exposed to Agent Orange and other tactical herbicides during the Vietnam War: however, the statements and conclusions made in both of these, in terms of the consumption of water distilled aboard ships while at sea, are contingent upon the assumption and requirement that tactical herbicides and the contaminant Tetrachlorodibenzo-p-dioxin (TCDD) were present in the water. VA's understanding of the science related to that issue, including the policies regarding the spray missions, the properties of the herbicides, the environmental fate of the herbicide components, and the expected behavior of the components in bodies of water off the coast of Vietnam, is that it is unlikely that this was a significant pathway of exposure to tactical herbicides for most Blue Water Navy Veterans.

Blue Water Navy Vietnam Veterans and Agent Orange Exposure, Institute of Medicine, 2011, pg 13, https://www.nap.edu/read/13026/chapter/2#13.

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Australian Study (Muller et al., 2002)

Researchers in Australia demonstrated it may have been possible to concentrate dioxin during the distillation of contaminated water, based on laboratory recreations of the major aspects of the distillation systems used aboard most ships during the Vietnam War. The theoretical nature of this series of experiments and differences in U.S. and Australian Naval policies at the time, however, restrict the extrapolation of these findings in terms of representing the experience of U.S. Navy Veterans who served on the offshore waters of Vietnam.

The authors attempted to determine this by recreating the major principles of the distillation system in a laboratory setting and assessing the potential for the co-distillation of several chemicals. It is important to note that most of the variables in the experiments, including the concentrations of chemicals, were not chosen to directly mirror the conditions in the offshore waters of Vietnam but rather to evaluate the effects of the physico-chemical properties of water and different types of compounds on distillation in this type of system. Thus, it was not meant to model the exposure scenario in Vietnam, but rather, the type of distillation system aboard the ships that were used. Based on the findings of the study, the authors concluded that "the distillation process of water contaminated with TCDD would result in contamination of potable water. Subsequent ingestion by sailors on board ships (as well as soldiers and airmen, who were passengers) is thus a vector for exposure to these chemicals. While it is unlikely that accurate exposure of the personnel on board ships can be estimated, the study findings suggest that the personnel on board ships were exposed to biologically significant quantities of dioxins." This conclusion may be appropriate for the Royal Australian Navy members who served during the war, as their protocol at that time was to draw water for drinking from turbid, estuarine type waters (or those closer to shore), which would include higher levels of salt, suspended particles, and potentially, contaminants from herbicide spray drift, while reserving the drawing of more pristine waters that were several miles off shore exclusively for their steam engines. The U.S. Navy protocol, however, was starkly different during that conflict. Per § 2.4.2 of the Naval Ships' Technical Manual (NAVMED P-5010-6; Department of the Navy, 1990). which is titled "Polluted Water," states that "unless determined otherwise, water in harbors, rivers, inlets, bays, landlocked waters, and the open sea within 12 miles of the entrance to these waterways, shall be considered to be polluted... The desalting of polluted harbor water or seawater for human consumption shall be avoided except in emergencies." Therefore, U.S. Navy ships that served only on the offshore waters several (at least 12) miles off the coast of Vietnam were not likely to have drawn contaminated water for drinking.

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2011 Institute of Medicine (IOM) Report

At the request of VA, IOM reviewed the evidence on this topic and issued a report in 2011. In this comprehensive review, the Committee detailed several factors that would affect the potential for TCDD-contaminated water to reach U.S. ships that were several miles offshore, including:

- It has been estimated that 87 percent of the Agent Orange sprayed reached the forest canopy, while only 13 percent was lost to drift, and of the 13 percent, an appreciable amount was likely degraded due to the Vietnamese environment.
- Agent Orange and TCDD would have entered waterways via riverbank spraying or runoff; however, a considerable fraction would absorb in organic materials that would be deposited in the delta regions or estuaries.
- Agent Orange and TCDD would have entered marine water from river discharge and spray drift; however, any amount in marine waters would be greatly reduced by the initial dilution in river water and dispersion in air and further dilution in coastal waters.

The Committee also reviewed the Australian study and considered another theoretical model that appeared to support its findings on the potential to concentrate TCDD through the distillation process. The Committee concluded that "it is theoretically possible to concentrate dioxin in distilled water, at least experimentally." While the Committee noted that, based on the available science, "if Agent Orange-associated TCDD was present in the marine water that U.S. ships drew for drinking water, distilled potable water would be a plausible pathway of exposure," they ultimately concluded that "without information on the TCDD concentrations in the marine feed water, it is impossible to determine whether Blue Water Navy personnel were exposed to Agent Orange-associated TCDD via ingestion, dermal contact, or inhalation of potable water." Additionally, regarding the Australian study, the Committee stated: "If the purpose of this experiment was to demonstrate the plausibility of TCDD exposure to sailors via distilled water, then this study is useful; however, the application of these findings to actual shipboard distillation systems requires knowledge of several factors not addressed in the experiment. The significance of this study's findings for contaminant exposures on Blue Water Navy ships is highly uncertain." Therefore, IOM did not corroborate the Australian study in terms of its applicability to U.S. Navy Veterans that served during the Vietnam War, but they noted that the study findings do support that the concentration of TCDD during distillation aboard ships is theoretically plausible. Current VA Study that may Provide Additional Scientific Evidence on Blue Water Navy

VA recently conducted a survey study on the health of Vietnam-era Veterans that included an "over-sampling" of Blue Water Navy Veterans as a subpopulation. The

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study will compare the health of this group to that of Vietnam Veterans, Vietnam-era Veterans, and the general U.S. population. In the absence of adequate exposure data, we hope to gain an understanding of the health of Blue Water Navy Veterans and may be able to make some determinations about whether outcomes they are experiencing could be related to exposure to tactical herbicides during their service. The results are currently being analyzed and are slated to be published as early as 2019.

Question 2: Why has VA denied claims for veterans who were exposed to Agent Orange if VA has records of specific ships and the veterans who were on those ships within the 12 mile demarcation line?

<u>VA Response</u>: Under current laws and regulations, there is not a 12-mile demarcation line for determining whether a vessel operated in the inland waterways.

Background:

Under the law, 38 United States Code § 1116, VA may only pay compensation for an Agent Orange-related disease for a Veteran determined to have "served in the Republic of Vietnam" during the period beginning on January 9, 1962, and ending on May 7, 1975. VA regulations, 38 Code of Federal Regulations § 3.307(a)(6)(iii), defines service in the Republic of Vietnam to only include service in the offshore waters if the service included duty or visitation in the Republic of Vietnam. VA has further clarified "service in the Republic of Vietnam" to consist of "boots on the ground" service or service in the inland waterways. VA's interpretation of "service in Vietnam", to include encompassing inland waterways, but excluding offshore waters has been upheld by the courts, to include the United States Court of Appeals for the Federal Circuit in its seminal decision in Haas v. Peake, 525 F.3d 1168 (Fed. Cir. 2008).

VA's regulatory definition of service in Vietnam excludes service in the offshore waters, as there is no evidence that Agent Orange was applied to the waters off the shore of Vietnam, nor is VA aware of any valid scientific evidence showing that individuals who served in the offshore waters were subject to the same risk of Agent Orange exposure as those who served in the geographic land boundaries of Vietnam.

Therefore, VA would not necessarily award benefits for a claim for disability compensation due to Agent Orange exposure for a Veteran who had served aboard a ship within 12 miles of the Vietnamese coast, as offshore service is not considered service in the inland waterways, which meets the statutory and regulatory definition of "service in Vietnam." Inland waterways include rivers, canals, estuaries, and deltas. Deep-water bays and harbors are not inland waterways but are considered to be offshore waters of Vietnam because of their deep-water anchorage capabilities and open access to the South China Sea. For example, we would consider service aboard a swift boat, landing ship, or tank to be service in the inland waterways because those

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types of vessels operated primarily on Vietnam's inland waterways. Agent Orange exposure would be conceded for any Veteran who served aboard this type of Naval vessel.

We also would concede exposure to Agent Orange if a Veteran who served in a ship operating in the offshore waters that temporarily entered an inland waterway. Additionally, we concede Agent Orange exposure if the ship docked to a pier or shore or was in the offshore waters and delivered personnel or supplies if there is evidence that the Veteran went ashore, as this was would be consistent with service that "involved duty or visitation in the Republic of Vietnam."

Medical Surgical Prime Vendor (MSPV) Program Reforms

My office has heard that the lack of a comprehensive approach to manage medical products throughout the VA system, could lead to an inefficient acquisition strategy for the Department. There have been efforts to revamp the MSPV program and I would like to know more about what the Department's next steps will be.

Question 3: What additional steps could VA take to reorganize the Medical Surgical Prime Vendor (MSPV) Program, and would VA use the Pharmaceutical Prime Vendor program as a model?

VA Response: VA should continue its efforts on multiple fronts now underway to improve the MSPV program, which are:

- The Veterans Health Administration (VHA) Healthcare Commodities Program Office (HCPO) near-term efforts to improve the MSPV program to increase VA medical centers (VAMC) and clinician access to the medical/surgical supplies required to treat patients, and improve flexibility for adding supplies to the list of available items, as feasible under legal and regulatory constraints. Simultaneously, we are pursuing longer term program goals that focus on leveraging VA's buying power to deliver more consistent, faster distribution services to the facilities, lower costs, and increase enterprise spend visibility via the MSPV 2.0 and our Clinically-Driven Strategic Sourcing (CDSS) initiative.
- The VHA CDSS initiative will improve processes and tools to better involve clinicians in identifying and validating supplies.
- The VHA HCPO's MSPV 2.0 effort is planning new, competitively awarded supply and distribution services contracts for Prime Vendors to improve VAMC with a more seamless and compliant, end-to-end supply chain solution focused

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on lowering costs, reducing acquisition wait times, and delivering essential supplies for Veteran care.

The VHA HCPO has been working closely with the Strategic Acquisition Center, Office of Small and Disadvantaged Business Utilization, and Office of General Counsel to ensure facility requirements and requests are pursued within relevant Federal Acquisition Regulations and Veterans Administration Acquisition Regulation framework and are compliant with legal statutes, which include the Rule of Two and Vets First.

- VHA is evaluating parts of the Pharmaceutical Prime Vendor (PPV) program for incorporation into the MSPV Program. One of the potential courses of action is to utilize the Federal Supply Schedules to make a larger market basket of medical surgical products available to all facilities.
- PPV program does currently rely on a single Prime Vendor to cover all regions, which is not the preferred approach for the VHA MSPV. VHA will propose to have more than one MSPV to reduce dependency risk. H.R. 5418, the Veteran Affairs Medical-Surgical Purchasing Stabilization Act, would set the expectation to have more than one prime vendor for VA medical/surgical supplies.
- The mechanism for communicating pharmaceutical prices to PPV may not be scalable for the volume of items that are required by the MSPV program. In the existing PPV model, the VA/National Acquisition Center (NAC) provides the prices electronically to PPV. PPV is only permitted to load prices provided by NAC. In the event the contracting office is delayed or unable to provide pricing, item availability may be at risk as MSPV would not have the information required to effectively procure the necessary items. Given that one of the key goals of the new MSPV program is to increase item availability, the risks associated with the current PPV model would run counter to the future intentions of HCPO.

Question 4: Has VA consulted with other interagency partners such as DoD?

VA Response:

 As part of the MSPV 2.0 program, we are analyzing different course of action for medical/surgical items – which include VA's Federal Supply Schedule and Defense Logistics Agency's (DLA) Distribution and Pricing Agreements (DAPA).

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Utilizing the DLA DAPA option is a possible solution that DLA has made available to VA.

- VHA views a partnership with DLA as a potential long-term solution given the comparable nature of the Department of Defense's (DoD) medical programs in terms of service and scope across hundreds of facilities; DLA's MSPV program is generally regarded as effective and efficient. VHA is including subject matter experts from DLA to assist in the MSPV 2.0 development efforts. DLA experts have shared best practices for their MSPV program and highlighted key differences between the two organizations to provide a more comprehensive understanding of the advantages and disadvantages of the different supply programs.
- As VA continues to explore migration to DoD's Defense Medical Logistics Supply System (DMLSS)/LogiCole solution to replace the legacy Integrated Funds Distribution, Control Point Activity, Accounting and Procurement system, the synergies of leveraging the DLA MSPV contract and DAPAs increase. A migration to DMLSS/LogiCole may need to include utilizing the DLA MSPV contracts, to achieve the efficiencies desired from this program.

<u>Question 5</u>: What steps would VA take to ensure the new program is staffed properly with individuals who have both clinical and medical supply chain expertise?

VA Response: CDSS initiative will be piloted next year to better leverage and integrate clinical, supply chain, and contracting expertise to provide clinicians with the medical supplies and equipment required to provide improved patient care for our Veterans. CDSS will include comprehensive and extensive coordination with the National Clinical Program Offices, clinicians, and supply chain personnel at both the facility and the Veterans Integrated Service Network levels. The strategy will be driven by clinician feedback and requests, and the supply catalog will include items that are safe, effective, and clinically sourced. Constant communication and transparency with clinicians is essential for the success of CDSS, and every CDSS-sourced medical item will leverage the medical expertise of our clinicians in the field.

Current VA Ordering Officer training materials will be updated to reflect lessons learned as well as the changes introduced by the MSPV 2.0 (future state) program.

Question 6: Would the reorganization include a program office to manage the new enterprise?

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<u>VA Response</u>: In June 2018, VA's Healthcare Commodities Program Office in its reorganization established a Medical/Surgical Future State effort to support the development of the MSPV 2.0 and other future medical/surgical programs. As the future MSPV program transitions from development to implementation and sustainment, additional reorganization may be required to best support the VAMCs.

<u>Question 7</u>: Would a reorganization require additional resources, either personnel or funding?

<u>VA Response</u>: VA will require additional resources, in the form of both personnel and funding, to support the MSPV 2.0 program as it moves into implementation and sustainment. Additional resources will be required to support a successful implementation, provide contract oversight and administration, and provide general program management support.

Question 8: Does VA need legislative language to facilitate a program reform?

<u>VA Response</u>: VA is reviewing ideas for legislation that could contribute to its efforts in these areas. We are glad to discuss potential improvements with the Committee.

VA U.S. Department of Veterana Affeirs			SUMMARY AND APPROVAL SHEET				
NAME OF ORIGINATOR Janna Holcomb (OCLA); (202) 461-620			VIEWS NO. 123032		10/30/2018 DATE DUE 11/05/2018		
NAME OF EXECUTIVE SEC Kimberly Sunds	Additional Questions for the Record (QFR): Senate Committee on Veterans' Affairs (SVAC) Legislative Hearing, August 1, 2018						
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EXECUTIVE SUMMARY

Purpose - Discussion - Recommendation

Purpose: To obtain SECVA concurrence for additional QFRs from the August 1, 2018, SVAC hearing prior to transmitting to the Office of Management and Budget (OMB) and SVAC.

Discussion: The enclosed document contains the Department's responses to eight QFRs from the August 1, 2018, SVAC hearing.

Recommendation: SECVA approves QFRs.